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- ii) **Short running title:** Effect of light intensity on image quality in endoscopic ear surgery: An experimental study
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## vi) Abstracts and Keywords:

### Objectives:

Endoscopic ear surgery is a rapidly developing field with many advantages. But endoscopes can reach temperatures of over 110 C at the tip, raising safety concerns. Reducing the intensity of the light source reduces temperatures produced. However, quality of images at lower light intensities has not yet been studied. We set out to study the effect of light intensity on image quality in EES.

### Design

Prospective study of patients undergoing EES from April to October 2016. Consecutive images of the same operative field at 10%, 30%, 50 % and 100% light intensities were taken. Eight international experts were asked to each evaluate 100 anonymised, randomised images.

**Setting:** District General Hospital

**Participants:** 20 patients

**Main Outcome Measures:** Images were evaluated on a five-point Likert scale (1= significantly worse than average; 5= significantly better than average) for detail of anatomy; colour contrast; overall quality; and suitability for operating.

### Results:

Mean scores for photographs at 10%, 30%, 50% and 100% light intensity were 3.22 (SD 0.93), 3.15 (SD 0.84), 3.08 (SD 0.88) and 3.10 (SD 0.86) respectively. In ANOVA models for the scores on each of the scales (anatomy; colour contrast; overall quality, and suitability for operating), the effects of rater and patient were highly significant ( $p < 0.0005$ ) but light intensity was non-significant ( $p = 0.34, 0.32, 0.21, 0.15$  respectively).

## **Conclusion:**

Images taken during surgery by our endoscope and operative camera have no loss of quality when taken at lower light intensities. We recommend the surgeon considers use of lower light intensities in endoscopic ear surgery.

**Key Words:** Endoscopes, Otologic Surgical Procedures, Hot Temperature, Image Enhancements

## **Introduction**

Endoscopic ear surgery (EES) is becoming increasingly adopted into practice.<sup>1</sup> Whereas the microscope remains external to the ear; the tip of the endoscope is passed through the external auditory canal. This has allowed surgeons to visualise hidden recesses such as the sinus tympani in great detail, and has improved our understanding of middle ear anatomy.<sup>2</sup>

Visual advantages are conferred from the proximity of the endoscope to middle and inner ear structures but concerns have been raised about the thermal effect of the light on the neurosensory cells of the inner ear.<sup>3</sup> Although the light source remains external to the body, thermal energy is transmitted along the endoscope from this source; endoscope-induced temperatures of up to 47 degrees Celsius has been measured at the round window in human temporal bone models maintained at body temperature.<sup>4</sup> These temperatures can rise rapidly, and reach 75 % maximal heat within less than two minutes of turning the light source on.<sup>4</sup>

Recommendations have therefore been made that light intensity should be reduced to the lowest possible whilst maintaining image quality for operating;<sup>4</sup> however, quality of images

at different light intensities has yet to be studied. We aim to study the effect of light intensity on image quality in EES.

## **Materials and Methods**

### *Ethical considerations*

This study has been reviewed by the South East Scotland NHS Research Ethics Committee.

### *Study design and setting*

This is a prospective study carried out in NHS Lanarkshire, Scotland from April to October 2016. All patients gave informed consent.

### *Patients, inclusion and exclusion criteria*

Twenty-five consecutive patients undergoing EES as part of their routine care were recruited pre-operatively in outpatient clinic. Inclusion criteria were age  $\geq 18$  years old; clinical indication for ESS; and ability to provide informed consent. Exclusion criteria were patients who declined participation in this study; and inability to give informed consent.

### *Equipment*

A 3 mm, 0 degree, 14 cm Hopkins rod (Karl Storz GmbH and Co., Tuttlingen, Deutschland) is routinely used for visualisation of the operative field in EES in our centre. L9000 LED light source (Stryker Endoscopy, San Jose, CA, USA) or a X800 Xenon Light source (Stryker

Endoscopy) was used. Selection of light source equipment was dependent upon the operating theatre used within our centre. A Stryker 1488 HD video camera was used for all cases.

At a point during the procedure, a period of 60 seconds or less was utilised to capture four photographs of the same operative field at 10 %, 30 %, 50 % and 100 % light intensity, respectively. For each patient, all other variables; i.e., light source; light cable; camera stack; were constant between photos. The primary operating surgeon held the endoscope still within the ear during this period, and a separate operating department practitioner adjusted light intensity and took photographs, to ensure stability of images. At no point during the procedure was the endoscope withdrawn, or the operative field changed, i.e., blood or secretions suctioned, between photographs. Photographs were quality controlled by the investigators (AI, RM) to ensure that operative field was unchanged between photographs.

The operative procedure was then carried out as scheduled and at the lowest light intensity required for adequate visualisation of the surgical field to perform the operation. This is usually 10% at our institution.

#### *Evaluation of operative photographs*

Four photographs, each at a different light intensity, from 25 patients were taken during the study period. The first 25 consecutive patients to consent to this study after ethical approval was granted were selected for this study, to limit any selection bias. Five patients were excluded from the study by investigators (AI, RM) using the criteria: significant difference in operating field between photographs at each light intensity; evidence of camera shake; or poor focus. Four photographs each from the 20 remaining patients were anonymised and

used to create a dataset of 80 photographs. One image from each of the 20 patients, at a randomly selected light intensity, was replicated; giving a dataset of 100 photographs. This dataset of 100 photographs was duplicated eight times; the order of these photographs in each of these eight datasets was individually randomised for assessor evaluation using computer randomisation.

Eight international experts in EES who are members of the IWGEES (International Working Group on EES) were asked to each evaluate an individually randomised dataset of 100 photographs on a five-point Likert scale (1=quality significantly worse than average; 5=quality significantly better than average) for four parameters. These four parameters were A., Detail of anatomy; B., Colour contrast; C., Overall quality and D., Suitability for operating. These raters were blinded to light intensity and patient for each photograph. Raters were deliberately not informed of duplicated photographs, added into the data set to assess intra-rater reliability. Images were viewed electronically on computer monitors. Raters were asked to rate all photographs in order and once only, in one sitting, so variables, such as the monitor used, were uniform for all 100 photographs.

#### *Statistical analysis*

Scores on each of the four scales were analysed using three-way analysis of variance (ANOVA) with the factors; rater, patient and light intensity. Each rater's first score for the replicated images was used in this analysis. For intra-rater agreement, a Cohen's kappa statistic was calculated, using both the original and replicated photographs for each rater

for each of the four parameters. The statistical package used was Minitab® 17 Statistical Software (Minitab Inc., State College, PA USA).

## Results

### *Subjects*

One set of four photographs was taken from each of the 20 patients to make the final dataset. Sets of photographs were taken of different procedures and pathology, which varied between patients; six sets were photographs of a middle ear taken during myringoplasty or before stapedectomy; two sets were photographs of a middle ear with extensive adhesions; four sets depicted extensive ossicular erosion secondary to cholesteatoma; two sets depicted a stapes prostheses in situ; and two sets demonstrated a glomus tympanicum within the middle ear. Four sets of photographs were of the tympanic membrane; of these, two were of tympanic membranes with visible keratin debris; and two were of uncomplicated perforations. In total, 10 sets of photographs were of the right ear; and 10 of the left ear. An example of one photo set is displayed (Figure 1).

### *Relationship between light intensity and quality*

Mean scores for photographs at 10%, 30%, 50% and 100% light intensity were 3.22 (Standard Deviation (SD) 0.93), 3.15 (SD 0.84), 3.08 (SD 0.88) and 3.10 (SD 0.86) respectively. Mean scores for all four scales (detail of anatomy; colour contrast; overall quality; suitability for operating) at the four light intensities studied are displayed in Table 1. In the ANOVA models, interaction terms between all, or any two of, intensity and rater and



patient were always highly non-significant. So, additive models were fitted; in all four scales (detail of anatomy; colour contrast; overall quality; suitability for operating) the effects of rater and patient were highly significant ( $p < 0.0005$ ) but light intensity was non-significant ( $p = 0.34, 0.32, 0.21, 0.15$  respectively). So, there was no significant difference in mean scores for different intensities after allowing for differences between raters and patients. Mean scores for all four parameters across all 20 patients are displayed in Figures 2-5.

#### *Intra-rater reliability*

Paired differences between first and second ratings for the repeated photographs were calculated for the four parameters. Mean differences were; detail of anatomy -0.01 (standard deviation (SD) 0.80); colour contrast 0.01 (SD: 0.80); overall quality 0.00 (SD:0.82), and suitability for operating 0.04 (SD:0.73). The results were also used to calculate kappa statistics for intra-rater agreement; detail of anatomy (kappa= 0.49); colour contrast (kappa=0.46); overall quality (kappa =0.37) and operating suitability (kappa=0.46). Kappa co-efficient is generally accepted as 'values  $\leq 0$  as indicating no agreement; 0.01–0.20 as none to slight; 0.21–0.40 as fair, 0.41– 0.60 as moderate, 0.61–0.80 as substantial; and 0.81–1.00 as almost perfect agreement'.<sup>5</sup> Therefore, intra-rater agreement for detail of anatomy, colour contrast, and suitability for operating was moderate; and for overall quality was fair.

## **Discussion**

#### *Synopsis of key findings*

The quality of images produced by the endoscope is secondary to several components; including light cable; light source; and camera head.<sup>6</sup> The only variable changed between the

four photographs taken of each subject within this study was the intensity of the light source; all other components were kept constant. Our results suggest that there is no relationship between image quality and light intensity for the images studied. In fact, the trend may indicate higher quality photographs within images taken at lower light intensities across all four domains, although this did not reach statistical significance (Table 1). The result for 'suitability for operating' is arguably the outcome of most importance, as this parameter is of immediate practical concern to the surgeon; mean scores at 10% were 3.28 (SD 0.98), and those at 100 % were 3.16 (SD 0.86), suggesting a trend towards better scores at the lower light intensities, although this is non-significant ( $p=0.15$ , Table 1).

#### *Clinical applicability of study*

Although no studies have yet directly investigated thermal damage secondary to clinical use of endoscopes in ear surgery, there is evidence to suggest sensitivity of the inner ear to high temperatures. It is known that an increase in body temperature to 39 degrees Celsius (C) reduces the amplitude of otoacoustic emissions, demonstrating temperature sensitivity of cochlear hair cells in humans.<sup>7</sup> There is also histological evidence to show alteration in cochlear vasculature and reduction in blood flow at 45 days after just 30 minutes of 40 C of body temperature, suggesting long-term cochlear damage from a relatively short period of hyperthermia.<sup>8</sup> A study of temporal bone models demonstrated an equivalent temperature rise at the lateral semicircular canal between water irrigated in the middle ear at 44 C during Caloric testing, and a 3 mm endoscope in the middle ear for around 300 seconds.<sup>9</sup> This suggests that heat produced by the endoscope is high enough to stimulate the vestibular system in a comparable manner to the Caloric.

There has also been research demonstrating herpes simplex virus type-1 (HSV-1) reactivation in the geniculate ganglion after two hours of exposure to 43 C heat.<sup>10</sup> Reactivation of HSV-1 is hypothesised to be responsible for delayed post-operative facial nerve palsy.<sup>10,11</sup> As the endoscope is capable of producing temperatures of this level,<sup>4</sup> there is a theoretical risk of facial nerve palsy after EES secondary to HSV-1.

Damage to tissues from direct contact with the endoscope tip has been well reported. Yavus et al provided histological confirmation of thermal damage at just 5 seconds of contact of bowel with the endoscope tip.<sup>12</sup> Whilst carrying out their study, Botrill et al., noted desiccation of mucosa after direct contact with the endoscope.<sup>9</sup> To this end, it has been recommended that the beginner in EES should not operate with their endoscope beyond the level of the annulus in order to prevent thermal injury.<sup>13</sup>

#### *Recommendations from other studies*

Due to these concerns, a number of studies have arisen with the aim of measuring variables influencing maximal temperatures produced by the endoscope.<sup>4,9,12,14,15,16</sup> Ito et al., measured a maximal temperature of 110 C at the tip of a 4 mm endoscope illuminated by a 100 % Xenon light source, but 61.5 C when the endoscope diameter was reduced to 2.7 mm.<sup>14</sup> Resultantly, this group recommended use of the endoscope at 2.7 mm diameter.<sup>14</sup> However, there are feasibility difficulties secondary to the restricted field of view produced, when using the endoscope at less than 3 mm diameter.<sup>13</sup>

Reducing light intensity or changing the nature of the light source may provide more practical solutions to reducing maximal temperatures.<sup>4,14</sup> Although the more efficient light-

emitting diode (LED) light source is now replacing the more traditional incandescent Xenon light source, heat still remains a concern.<sup>14</sup> At 100 % intensity, the heat at the tip of a 4 mm endoscope with a Xenon light source is 110 C, whereas the heat at the tip of the same endoscope with a LED light source is still 64.9 C.<sup>14</sup> Kozin et al., had found that using an endoscope with a Xenon light source at 50 % intensity compared to 100 % reduced maximal temperatures from around 47 C to 42 C at the round window in temporal bone models.<sup>4</sup> With use of the LED light source, maximal temperatures were further reduced to around 45 C and 41 C at 100 % and 50 % light intensity respectively.<sup>4</sup> In guinea pig temporal bones, another group reported that when intensity of the light source is reduced to 50 %, temperatures fell to 35 % of maximal.<sup>15</sup> Therefore, these groups have all recommended reducing light intensity to the lowest possible level.<sup>4,14,15</sup>

#### *Explanation of results*

To date, no other groups have studied image quality at different intensities within EES. We hypothesise that the technology within our camera systems accommodates for changes in light intensity within the middle ear, such that it diminishes differences between photographs. In the field of digital photography, image quality can be maintained in lower lighting levels by adjusting shutter speed, aperture size and ISO, the camera's sensitivity to light; these functions can be controlled both manually and automatically.<sup>17</sup> Camera technology within surgery has also advanced in parallel; the 1488 HD Stryker camera used by our unit takes pictures with an automated shutter speed of 1/60 to 1/50000 seconds;<sup>18</sup> and company promotional literature for this camera makes assertions of 'enhanced light sensitivity to allow the light source to run at lower power levels whilst still providing premium optical

performance'.<sup>19</sup> Our results would also support the use of lower light intensity levels, whilst maintaining image quality, for this camera system.

#### *Limitations of our study*

This study depends upon subjective measurements of image quality. Within our study, intra-rater agreement was fair to moderate as measured by kappa.<sup>5</sup> A recent study of rater evaluation of digital images of retraction pockets, where the rater was asked to classify retraction pockets by the Tos and Sade classification systems, again found intra-rater agreement to be fair to moderate; this is despite these classification systems being well established and in widespread use.<sup>20</sup> Therefore, although we accept that intra-rater reliability is a limitation to this study, the authors judge that our raters have reasonable enough intra-rater agreement to substantiate the overall results.

We reported our experience with our particular camera; therefore, our results may not be generalizable to all systems. The use of percentages of light intensity are relative, rather than absolute, in this study, and are again specific to our particular set-up. A study conducted to examine image quality at absolute measures of light intensity would provide more generalisable results.

#### *Conclusion*

This study provides a demonstration that higher endoscopic light intensities do not always equate to higher quality images. Therefore, we recommend the surgeon reduces the light intensity to the lowest possible for their particular camera system, whilst maintaining quality of the image, to help reduce risk of tissue damage to structures of the middle and inner ear. This was as low as 10 % in our study.

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### Figure legends

**Table 1:** Overall Results: Mean scores, calculated from all 8 rater's scores, for each category at the four light intensities studied. Raters were asked to evaluate each photograph on a 5 point Likert score (1=significantly worse than average; 5=significantly better than average). SD= Standard Deviation.

**Figure 1:** Set of four endoscopic photographs taken intra-operatively from one patient of the same operative field within a 60 second time frame. Intensities (clockwise from top left) 10 %, 30 %, 50 %, 100 %. Four photographs from 20 patients were used for the final data set.

**Figure 2:** Mean rater scores for evaluation of detail of anatomy for each of the 20 patient photograph sets taken with the endoscope. Raters were asked to evaluate each photograph on a 5 point Likert score (1=significantly worse than average; 5=significantly better than average). Lines correspond to light intensity as per figure legend. Effect of light intensity on score did not reach significance for this parameter ( $p=0.34$ ).

**Figure 3:** Mean rater scores for evaluation of colour contrast for each of the 20 patient photograph sets taken with the endoscope. Raters were asked to evaluate each photograph on a 5 point Likert score (1=significantly worse than average; 5=

significantly better than average). Lines correspond to light intensity as per figure legend. Effect of light intensity on score did not reach significance for this parameter ( $p=0.32$ ).

**Figure 4:** Mean rater scores for evaluation of overall quality for each of the 20 patient photograph sets taken with the endoscope. Raters were asked to evaluate each photograph on a 5 point Likert score (1=significantly worse than average; 5=significantly better than average). Lines correspond to light intensity as per figure legend. Effect of light intensity on score did not reach significance for this parameter ( $p=0.21$ ).

**Figure 5:** Mean rater scores for evaluation of suitability for operating for each of the 20 patient photograph sets taken with the endoscope. Raters were asked to evaluate each photograph on a 5 point Likert score (1=significantly worse than average; 5= significantly better than average). Lines correspond to light intensity as per figure legend. Effect of light intensity on score did not reach significance for this parameter ( $p=0.15$ ).

	Intensity (%, percentage)							
	10%		30%		50%		100%	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
<b>Detail of Anatomy</b>	<b>3.24</b>	0.99	<b>3.19</b>	0.95	<b>3.12</b>	1.01	<b>3.11</b>	0.99
<b>Color Contrast</b>	<b>3.16</b>	1.03	<b>3.07</b>	0.96	<b>3.04</b>	0.95	<b>3.01</b>	0.97
<b>Overall quality</b>	<b>3.22</b>	0.98	<b>3.10</b>	0.86	<b>3.07</b>	0.91	<b>3.11</b>	0.89
<b>Suitability for Operating</b>	<b>3.28</b>	0.98	<b>3.22</b>	0.89	<b>3.11</b>	0.92	<b>3.16</b>	0.86









